IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9380

Bartle, J. December 16, 2014

Sheila J. Walsh ("Ms. Walsh" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for supplemental Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2013, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Michael M. Neumann, M.D. Based on an echocardiogram dated March 25, 2002, Dr. Neumann attested in Part II of Ms. Walsh's Green Form that she suffered from severe mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation,[3] an abnormal left ventricular end-systolic

---

2. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Neumann also attested that claimant suffered from New York Heart Association Functional Class IV Symptoms. This (continued...)

dimension, an abnormal left atrial dimension, a reduced ejection fraction of less than 30%,[4] and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.[5] Based on such findings, claimant would be entitled

---

3. (...continued)
condition is not at issue in this claim.

4. In claimant's Green Form, Dr. Neumann indicated that claimant suffered a stroke that resulted in a permanent condition that meets the criteria for Functional Level V of the AHA Stroke Outcome Classification System. In a subsequent handwritten note, Ms. Walsh withdrew her claim as to this condition.

5. In addition, Dr. Neumann attested that Ms. Walsh suffered from ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) where surgery was not performed because it was medically contraindicated and was in a persistent non-cognitive state caused by a complication of valvular heart disease or valvular repair/replacement surgery. A claimant is entitled to Level V Matrix Benefits if he or she qualifies for Level I(b), III, or IV benefits and is in a persistent non-cognitive state caused by a complication of valvular heart disease or valvular repair/replacement surgery. See Settlement Agreement § IV.B.2.c.(5)(b)v); Seventh Amendment § I.B.30.b. Although the Trust does not dispute that Ms. Walsh is in a persistent non-cognitive state, the Trust does dispute that she has a condition that qualifies for Level III benefits, namely, that she had ACC/AHA Class I indications for surgery to repair or replace the aortic and/or mitral valve(s) where the surgery was not performed because it was medically contraindicated. Given our disposition with regard to claimant's other medical conditions, we need not resolve this dispute.

to Matrix A-1, Level V[6] benefits in the amount of $1,124,502.[7]

In November, 2013, the Trust forwarded Ms. Walsh's claim for review by M. Michele Penkala, M.D., one of its auditing cardiologists. In audit, Dr. Penkala concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Walsh had ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. In support of this conclusion, Dr. Penkala explained:

> As detailed in the note from Dr. Paul Levine dated 9/25/12 the patient had a [biventricular automated implantable cardioverter-defibrillator] implanted for primary prevention. Although she was documented to have several brief nonsustained [ventricular tachycardia] 4-6 beats in duration during period 3/16/11-3/18/11, she did NOT have sustained [ventricular tachycardia] or [ventricular fibrillation] that was ever documented either prior to or after placement of her device on 3/25/11.

---

6. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A claimant qualifies for Level II benefits if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.c.(2)(b). The Trust does not contest that Ms. Walsh qualified for Level II benefits.

7. Ms. Walsh previously was paid Seventh Amendment Category One benefits. Thus, if her supplemental claim for Matrix A-1, Level V benefits is payable, Ms. Walsh will only receive the amount that exceeds the previous payment she received. See Settlement Agreement § IV.C.3.

Pursuant to Court Approved Procedure No. 11, the Consensus Expert Panel[8] subsequently reviewed Ms. Walsh's claim. The Consensus Expert Panel found:

> [N]o [reasonable medical basis] for the attesting physician's finding of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. In this case, the ventricular fibrillation was intentionally induced as a routine part of the testing of the [implantable cardioverter-defibrillator], and did not occur as a spontaneous arrhythmia; this differs from ventricular fibrillation that may occur with surgical handling of the heart or upon separation from cardiopulmonary bypass.[9]

Based on the auditing cardiologist's and the Consensus Expert Panel's findings, the Trust issued a post-audit determination denying Ms. Walsh's claim.[10] Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"),

---

8. The Consensus Expert Panel consists of three cardiologists, one designated by each of Class Counsel, the Trust, and Wyeth. See Pretrial Order ("PTO") No. 6100 (Mar. 31, 2005). We approved creation of the Consensus Expert Panel to "monitor the performance of the Auditing Cardiologists and to develop procedures for quality assurance in the Audit of Claims for Matrix Compensation Benefits." Id.

9. The report of the Consensus Expert Panel is not in the Show Cause Record. The Trust only provided an excerpt of the Consensus Expert Panel's finding in its post-audit determination.

10. The Trust also included correspondence from Wyeth and Class Counsel dated May 19, 2014. As the Settlement Agreement is not ambiguous, the intent of the parties is irrelevant to the disposition of this claim. See In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 525 F. App'x 140 (3d Cir. 2013) (citation omitted).

claimant contested this adverse determination.[11] In contest, claimant argued that her medical records provided a reasonable medical basis for her claim.

The Trust then issued a final post-audit determination, again denying Ms. Walsh's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On September 5, 2014, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 9349 (Sept. 5, 2014).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 10, 2014, and claimant submitted a sur-reply on November 15, 2014. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

---

11. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Walsh's claim.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for her claim. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Walsh reasserts that there is a reasonable medical basis for Dr. Neumann's finding that she had ventricular fibrillation. In response, the Trust argues that claimant did not "suffer from" ventricular fibrillation as required by the Settlement Agreement because claimant "did not have ventricular fibrillation that was ever documented either prior to or after placement of her [automated implantable cardioverter-defibrillator] device on March 25, 2011."

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for finding that she suffered ventricular fibrillation as required by the Settlement Agreement. As stated previously, a claimant is entitled to Level V benefits if "[t]he individual otherwise qualifies for payment at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular

tachycardia which results in hemodynamic compromise." Settlement Agreement § IV.B.2.c.(5)(d). The Trust does not contest that claimant qualifies for payment at Matrix Level II. Also, the Show Cause Record reflects that claimant suffered from ventricular fibrillation. In particular, the March 25, 2011 Cardiac Catheterization Report for claimant specifically notes the occurrence of the required medical condition of ventricular fibrillation for Level V benefits:

> Intraoperative EP testing and DFT determination was then performed. Ventricular fibrillation was then induced using a shock on T after 8 beats of pacing train introduced. The patient went into ventricular fibrillation which was then shocked to normal sinus rhythm with 20 joules successful shock, with optimal charge time and impedance. The patient was then taken to the recovery area in excellent condition.

The Trust, however, argues that the episode of ventricular fibrillation Ms. Walsh experienced does not support a claim for Level V benefits because the Settlement Agreement was not intended to provide compensation for a "single incident of ventricular fibrillation that was purposely created as part of [claimant's] treatment."[12] In addition, the Trust contends that the ventricular fibrillation Ms. Walsh suffered is not compensable because it "was intentionally induced as a routine part of the testing of the [implantable cardioverter-

---

12. The fact that claimant only experienced ventricular fibrillation once is irrelevant. The plain text of the Settlement Agreement only requires that claimant "suffers from ventricular fibrillation," which she did on March 25, 2011.

defibrillator], and did not occur as a spontaneous arrhythmia ...." We disagree.

We have previously rejected the Trust's argument that ventricular fibrillation must occur spontaneously to be compensable under the Settlement Agreement. Specifically, in PTO No. 8624, we held that the Trust's argument that claimant was not entitled to Level V benefits because the ventricular fibrillation she experienced was "not spontaneous, but rather 'was induced by manipulation of the heart ... during surgery'" improperly required proof of causation. Mem. in Supp. of PTO No. 8624, at 17-18 (Mar. 9, 2011); see also Mem. in Supp. of PTO No. 9078, at 8-10 (May 30, 2013); Mem. in Support of PTO No. 9141, at 15 (Sept. 18, 2013).

The present case is not distinguishable from these precedents. We recognize that the Trust's current argument is a variation of the "spontaneous" argument we previously rejected as inconsistent with the Settlement Agreement.[13] If "induced" ventricular fibrillation satisfies the requirements of the Settlement Agreement, "intentionally induced" ventricular fibrillation is similarly sufficient.

This result also is consistent with our previous decisions that causation generally is not at issue in resolving claims for Matrix Benefits. Rather, a claimant must show that he

---

13. The Consensus Expert Panel concluded that there was no reasonable medical basis for Ms. Walsh's claim because her ventricular fibrillation was "intentionally induced" and "did not occur as a spontaneous arrhythmia."

or she meets the objective requirements set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred ....

Mem. in Supp. of PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

> ... [Individual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97.

The only objective requirement of Section IV.B.2.c.(5)(d) of the Settlement Agreement is that claimant suffers from ventricular fibrillation. It does not require any proof that the Diet Drug Recipient suffered from ventricular fibrillation that was caused by Diet Drug use. Nor does it require that the ventricular fibrillation result from "spontaneous arrhythmia" or unintentional or unanticipated circumstances. We must apply the Settlement Agreement as written. Accordingly, the Trust's assertion that ventricular fibrillation experienced during the course of claimant's medical treatment must have been spontaneous or unintentional in order to satisfy the requirements of Section IV.B.2.c.(5)(d) of the Settlement Agreement is erroneous.

For the foregoing reasons, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for her claim. Therefore, we will reverse the Trust's denial of Ms. Walsh's claim for Matrix A-1, Level V benefits.